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UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY

DEPOMED, INC.,

Plaintiff,

v.

ACTAVIS ELIZABETH LLC et al.,

Defendants.

No: 3:12-CV-01358 JAP (TJB)

**MEMORANDUM OF LAW IN  
SUPPORT OF DEPOMED INC.'S  
MOTION IN LIMINE NO. 2 TO  
EXCLUDE TESTIMONY ON  
PREVIOUSLY UNDISCLOSED  
OPINIONS**

**Honorable Joel A. Pisano**

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## **I. INTRODUCTION**

Plaintiff Depomed, Inc. (“Depomed”) seeks the Court’s intervention to ensure that Defendants’ experts do not proffer testimony on issues that they did not address in their expert reports and were not prepared to provide during their depositions. Specifically, Depomed moves to exclude testimony of Defendants Actavis Elizabeth LLC’s and Actavis LLC’s (collectively, “Actavis”) experts (a) Dr. Flanagan and Dr. Mayersohn on their responses to Depomed experts’ rebuttal reports and (b) Dr. Sinatra on new opinions that he may form between his deposition and before trial. Drs. Flanagan, Mayersohn and Sinatra each have indicated that they might proffer previously undisclosed opinions at trial, even though they did not disclose them in their expert reports and were unprepared or unwilling to provide their opinions during deposition. Allowing such testimony would be unfairly prejudicial to Depomed and contrary to well-established rules.

## **II. A PARTY IS ENTITLED TO LEARN BEFORE TRIAL THE SUBSTANCE OF ANY OPINIONS AN OPPONENT’S EXPERT PLANS TO OFFER AT TRIAL**

Like other of the “various instruments of discovery” permitted under the Federal Rules of Civil Procedure, depositions are intended to permit the parties to “narrow and clarify the basic issues” and also to avoid surprise by “obtain[ing] the fullest possible knowledge of the issues and facts before trial.” *Hickman v. Taylor*, 329 U.S. 495, 501 (1947). To this end, the Federal Rules provide that the party

against whom an expert's testimony will be offered is entitled to learn the contents of that expert testimony before trial and those experts should be bound to that testimony at trial. Federal Rule of Civil Procedure 26(a)(2)(B)(i) ("Rule 26(a)(2)(B)(i)") provides that an expert's report must contain "a complete statement of all opinions the witness will express and the basis and reasons for them." Federal Rule of Civil Procedure 26(b)(4)(A) ("Rule 26(b)(4)(A)") provides that a party is entitled to depose its opponent's experts on any opinions the experts may present at trial. *See also* Fed. R. Civ. P. 26(b)(4)(A) advisory committee's note (1970) ("A party can require one who intends to use the expert to state the substance of the testimony the expert is expected to give."). Pursuant to Federal Rule of Civil Procedure 26(e)(2), ("Rule 26(e)(2)") a party's duty to supplement extends to the information provided in an expert report and during deposition. Fed. R. Civ. P. 26(e)(2).

### **III. EXCLUSION OF UNDISCLOSED OPINIONS IS APPROPRIATE UNDER RULES 37(c)(1) AND/OR 403**

#### **A. EXCLUSION OF UNDISCLOSED OPINIONS IS MANDATORY UNDER RULE 37(c)(1)**

Federal Rule of Civil Procedure 37(c)(1) ("Rule 37(c)(1)") provides that "if a party fails to provide information...as required by Rule 26(a), . . . the party is not allowed to use that information or witness to supply evidence...at a hearing[] or at a trial, unless the failure was substantially justified or is harmless." Where a party

wishes to supplement its expert testimony, it must do so through Rule 26(e), and failure to do so according to Rule 26(e) also is subject to the mandatory exclusionary sanction of Rule 37(c)(1). While Rule 37(c)(1) provides for increasing or lessening the severity of sanctions for failure to disclose expert testimony on a motion, the default sanction is exclusion. Fed. R. Evid. 37(c)(1).

Many courts have excluded testimony of undisclosed expert opinions and bound experts to their opinions and deposition testimony to prevent violations of Rule 26 at trial. The reasoning for doing so in *Walsh v. McCain Foods Ltd.* is instructive. 81 F.3d 722, 727 (7th Cir. 1996). There, the defendant's expert was unable to answer questions regarding an exhibit cited in his report.<sup>1</sup> *Id.* Following the deposition, the defendant "neither supplemented [the expert's] deposition nor the written report" as required by Rule 26. *Id.* The court affirmed the District Court's ruling that the defendant's expert was bound at trial to the statements he made in his report and during his deposition and that the defendant "cannot legitimately argue

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<sup>1</sup> *Walsh* was decided in 1996, when exclusion of materials not disclosed in connection with expert disclosures was discretionary. The mandatory exclusionary sanction of Rule 37(c)(1) applied to expert disclosures via rule change in 2000. *See* Fed. R. Civ. P. 37 advisory committee notes (2000). Thus, the *Walsh* court's noting that exclusion of undisclosed expert testimony is discretionary is inapplicable here, as exclusion is now mandatory absent substantial justification or harmlessness. 81 F.3d at 727 ("Additionally, if a party fails to comply with Rule 26, a trial court has the discretion to apply sanctions [to exclude undisclosed expert testimony], including the exclusion of evidence."); Fed. R. Civ. P. 37(c)(1).

that [the expert] should have been allowed to testify about matters not previously disclosed to the plaintiffs.” *Id.*

#### **B. RULE 403 SUPPORTS EXCLUSION OF UNDISCLOSED EXPERT OPINIONS**

Federal Rule of Evidence 403 (“Rule 403”) also compels exclusion of undisclosed expert opinions. While not enumerated by the rule, unfair surprise is a type of unfair prejudice that can compel the exclusion of relevant evidence.<sup>2</sup> *See, e.g., U.S. v. Price*, 13 F.3d 711, 719 (3d Cir. 1994); Fed. R. Evid. 403 advisory committee notes (1972)).

#### **IV. THE COURT SHOULD EXCLUDE REPLY OPINION TESTIMONY OF DR. FLANAGAN AND DR. MAYERSOHN ON ALLEGED INVALIDITY OF THE ASSERTED PATENTS**

Actavis’s experts and/or Actavis have frustrated Depomed’s attempts to learn any rebuttal testimony of Actavis’s two invalidity experts, Drs. Flanagan and Mayersohn in response to Depomed’s invalidity experts’ rebuttal reports (*i.e.*, their

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<sup>2</sup> This case can be distinguished from the few decisions in which courts have stated that the unfair prejudice aspect of Rule 403 does not apply in bench trials. *See Gulf States Utils. Co. v. Ecodyne Corp.*, 635 F.2d 517, 519 (5th Cir. 1981); *I.B.E.W. Local Union 380 Pension Fund v. Buck Consultants*, C.A. No. 03-4932, 2008 WL 2265269, at \*3 (E.D. Pa. June 3, 2008); *Hussey v. Chase Manhattan Bank*, C.A. No. 02-7099, 2005 WL 2203146, at \*7 (E.D. Pa. July 29, 2005); *Schultz v. Butcher*, 24 F.3d 626, 631-32 (4th Cir. 1994). Whereas in this case Depomed has not had the opportunity to vet through fact discovery the evidence it seeks to exclude and is subject to unfair surprise if that testimony is admitted, in those cases the litigants had their opportunities to vet the evidence (as they would in the typical case) and moved to exclude simply because the evidence was prejudicial to their cases. As such, the moving parties in those cases were not likely to be unfairly prejudiced by unfair surprise.



“reply” expert opinions on invalidity (or “reply opinions”). Yet, they have indicated that they will provide reply opinions at trial. Drs. Flanagan and Mayersohn have been retained by Actavis to opine whether the asserted claims are obvious over certain identified prior art references and also to respond to Depomed’s experts’ opinions as to any secondary indicia of nonobviousness. Pursuant to the Scheduling Order of January 29, 2014 (ECF No. 254), Actavis served invalidity expert reports by Drs. Flanagan and Mayersohn on Depomed February 26, 2014. On March 19, 2014 (ECF No. 254), Depomed served rebuttal expert reports on the validity of the asserted patent claims. Expert depositions commenced thereafter.

Depomed deposed Dr. Flanagan on April 2, 2014, more than two weeks after Depomed served its rebuttal reports. (Ex. 7 at 1.)<sup>3</sup> Dr. Flanagan testified that he reviewed Depomed’s experts’ rebuttal reports “quick[ly]” and “cursor[ily]” in the two weeks between the day Depomed served those reports and the day on which he was deposed. (*Id.* at 9:9-10:13.) Dr. Flanagan testified that he had not “reviewed [Depomed’s rebuttal reports] in detail” sufficient to determine whether they changed his opinions. (*Id.*) He suggested that he will be prepared to offer additional reply opinions at trial. (*Id.* at 9:15-18 (“I am not sure I am prepared to [respond to Depomed’s rebuttal reports] **at this time.**”) (emphasis added), 9:23-25 (“No, I would

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<sup>3</sup> Citations to “Ex. \_” are to the exhibits attached to the Declaration of Daniel K. Greene In Support of Depomed, Inc.’s Motion *In Limine* Nos. 1-6 filed concurrently herewith.

prefer not to [provide any rebuttal to Dr. Hopfenberg's rebuttal report] *at this time.*") (emphasis added)). Depomed reserved the right to depose Dr. Flanagan about any reply opinions. (*Id.* at 10:1-3.)

Depomed deposed Dr. Mayersohn on March 24, 2014, and he too was not prepared to discuss Depomed's experts' rebuttal reports. Underscoring Actavis's own understanding that its experts needed to be prepared to testify on any rebuttal opinions, Actavis's lawyer asked Dr. Mayersohn if he was "prepared today to testify regarding any responses you might have at this point to those reports." (Ex. 9 at 249:18-20.) In response, he replied, "if necessary." (*Id.* at 249:19.) On redirect, after some questions, he testified that he was "not prepared to testify" on Depomed's rebuttal reports and acknowledged his prior testimony on preparedness to do so was in "error." (*Id.* at 252:6-25.) Dr. Mayersohn reviewed Depomed's experts' rebuttal reports in a "trivial way, but not substantially." (*Id.* at 251:23-253:2.) Dr. Mayersohn did indicate that he would be prepared to provide his reply opinions at trial, however. (*Id.* at 249:6-24, 252:20-25.)

There is no justification for Drs. Mayersohn's and Flanagan's unpreparedness to provide their reply opinions. Even Actavis's counsel appears to have expected Dr. Mayersohn to be ready to testify on this topic, given his questioning of Dr. Mayersohn on this topic during redirect. (*Id.* at 249:6-24.) Given this line of questioning to Dr. Mayersohn, Dr. Flanagan, who was deposed a week later, also

should have expected such questions and been prepared to testify as to any reply opinions.

Further, Drs. Mayersohn and Flanagan had sufficient time to formulate their reply opinions. Dr. Flanagan had two weeks, while Dr. Mayersohn had about four days.<sup>4</sup> Given that Mayersohn's opinion was much more circumscribed than that of Dr. Flanagan (Dr. Mayersohn opined only with respect to the WO '128 reference and only pertaining to the pharmacokinetic element in the asserted claims of only three of seven patents), four days should have been sufficient. Importantly, these reply opinions relate to Depomed's experts' rebuttals to Drs. Flanagan's and Mayersohn's opening reports, and so Drs. Flanagan and Mayersohn were already familiar with the subject matter that would form the basis of any reply opinion.

In sum, Drs. Mayersohn and Flanagan should have been prepared to, and had sufficient time to prepare their reply opinion, but chose not to, thereby preventing Depomed from knowing the scope and nature of their opinion as required by the Federal Rules.

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<sup>4</sup> Actavis chose to make Dr. Mayersohn available on that date; Depomed did not insist on the date. Further, Actavis provided only one date each for Dr. Flanagan's and Dr. Mayersohn's depositions. (Ex. 8 (email from Jason Murata to William Gaede (March 7, 2014, 3:08 PM)).) Depomed accepted these dates.

**A. THE COURT SHOULD EXCLUDE REPLY TESTIMONY UNDER RULE 37(c)(1)**

There can be no question that any testimony of previously undisclosed expert opinions violates the requirements of Rule 26(a)(2)(B)(i) that Actavis provide a complete statement of all expert opinions and the requirement of Rule 26(e)(2) for supplementation of expert opinions and deposition testimony. As noted above, this violation subjects Actavis to automatic exclusion of testimony of previously undisclosed expert opinions under Rule 37(c)(1). *See also Invista N. Am. S.A.R.L. v. M & G USA Corp.*, Civ. No. 11-1007, 2013 WL 3216109, at \*2 (D. Del. June 25, 2013).

Actavis cannot carry its burden to demonstrate that the inabilities Dr. Flanagan or Dr. Mayersohn to provide their reply opinions during their depositions are either substantially justified or harmless, which are the only ways Actavis can avoid the mandatory exclusion of Rule 37(c)(1). *See Fed. R. Civ. P. 37(c)(1); Am. Stock Exchange LLC v. Mopex, Inc.*, 215 F.R.D. 87, 93 (S.D.N.Y. 2002) (setting forth burdens). Depomed is hard pressed to find any justification - much less substantial justification - for these failures, in view of the fact that both experts should have expected to have been questioned and had plenty of time to consider Depomed's experts' rebuttal reports prior to their depositions. What's more, Depomed's rebuttal reports responded to Dr. Flanagan's and Dr. Mayersohn's

opening reports, so Drs. Flanagan and Mayersohn were already familiar with the subject matter of Depomed's rebuttals.

Nor can Actavis show harmlessness. In this Circuit, harmlessness is determined by weighing the *Pennypack* factors. No one *Pennypack* factor is dispositive, and the Court should look to the overall balance of the factors when assessing harmlessness. The *Pennypack* factors are the: (1) importance of information withheld; (2) prejudice or surprise to the party against whom the evidence is offered; (3) likelihood of disruption of the trial; (4) possibility of curing the prejudice; (5) explanation for the failure to disclose; and (6) the presence of bad faith or willfulness in not disclosing the evidence. *See Meyers v. Pennypack Woods Home Ownership Ass'n*, 559 F.2d 894, 904-05 (3d Cir. 1977), *overruled on other grounds*, *Goodman v. Lukens Steel*, 777 F.2d 133 (3d Cir. 1985). All of the *Pennypack* factors weigh in Depomed's favor:

- *Pennypack* Factor (1): Drs. Flanagan and Mayersohn are the only witnesses that Actavis "will" provide testimony from, according to Actavis' disclosure of its witness list. Only Drs. Flanagan and Mayersohn provided opening invalidity expert reports on behalf of Actavis. As such, any new theory or interpretation of the references that Drs. Flanagan and Mayersohn may provide during trial is likely to have significant ramifications, both to Depomed and Actavis.
- *Pennypack* Factors (2) – (4): Depomed will have no opportunity to vet these theories prior to trial. And because this case is on the eve of trial and the 30 month stay is nearly up, it is impossible for Depomed to cure this prejudice. *See Fed. R. Evid. 403 advisory committee notes (1970)* ("[T]he granting of a continuance is a more appropriate remedy than exclusion of the [unfairly surprising] evidence.").

- *Pennypack* Factors (5) and (6): In view of the time Actavis's experts had to prepare to explain any reply opinions during their depositions, there likely is no reason to excuse these failures.<sup>5</sup>

This Court has granted under Rule 37(c)(1) the relief Depomed is requesting in similar circumstances. *E.g., Reckitt Benckiser Inc. v. Tris Pharma, Inc.*, C.A. 09-3125, 2011 WL 6722707, at \*7-9 (D.N.J. Dec. 21, 2011) (affirming *Pennypack* analysis and striking supplemental expert report served after the close of expert discovery).

#### **B. THE COURT SHOULD EXCLUDE UNDER RULE 403**

The Court should also exclude for reasons of unfair surprise any proffered testimony of Dr. Flanagan or Dr. Mayersohn about any undisclosed reply opinions. Even though it is entitled to know the substance of all of Dr. Flanagan's and Dr. Mayersohn's testimony before trial, obviously Depomed cannot prepare for opinions not disclosed in accordance with the governing rules. *See* Fed. R. Evid. 403; Fed. R. Civ. P. Rule 26(a)(2)(B)(i), 26(b)(4)(A). Actavis should not be permitted to hide the ball in this manner, and any reply opinions should be excluded.

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<sup>5</sup> By contrast, Depomed made sure that its experts were prepared to testify at deposition on any rebuttal reports of Actavis, thereby providing Actavis with a fair opportunity to discover any reply opinion in response to the rebuttal opinion. Actavis's approach intentionally leaves Depomed in the dark and thus permits Actavis to sandbag at trial.

**V. THE COURT SHOULD EXCLUDE ANY TESTIMONY BY DR. SINATRA OF PREVIOUSLY UNDISCLOSED OPINIONS**

Should the Court decide not to strike the entire report of Dr. Sinatra and exclude any testimony thereto for failure to comply with *Daubert* (see Motion *In Limine* No. 5), the Court nevertheless should exclude Dr. Sinatra from testifying as to any previously undisclosed opinions, such as the opinions he apparently intends to form after his deposition and before trial:

Q. Will you be offering at trial any opinions that are not contained in your report that you have in front of you?

A. Well, I think I deserve the right to do additional research and reading. I may come up with other ideas.

Q. Okay. Have you been instructed to do additional research and reading, or, I shouldn't say instructed, have you been requested to do additional research and reading?

A. No.

Q. Do you plan to do any additional research and reading?

A. I may, yes.

(Ex. 10 at 47:6-19.)

What's more, the research Dr. Sinatra "may" do is research he could and should have already done because it is fundamental to any opinion as to the absence of a long felt but unmet need for an extended release gabapentin formulation. Specifically, Dr. Sinatra testified that he

may want to do some research as to any advantages that an extended gastric retained dosage can offer to patients. I might want to do a pharmacoeconomic analysis, is there a benefit? Is there any long-term

data to suggest that patients on gastric retained dose do better than current therapy, which is either entry level gabapentin or Neurontin or, I am sorry, pregabalin.

(*Id.* at 47:20-48:4.) Dr. Sinatra admitted that he did not do the potential research before he prepared his report in rebuttal to Depomed's expert Dr. Michelle Brown's expert report and that he would not limit his research to sources that became available only after the date of his deposition. (*Id.* at 49:6-50:6.) Dr. Sinatra states that he "just didn't [do the research] at the time." (*Id.* at 50:8-15.)

The Court should exclude Dr. Sinatra from testifying about any opinions other than those set forth in his expert report. Depomed unquestionably is entitled to learn about any opinion Dr. Sinatra intends to offer at trial before trial. (*See* Section II, *supra*.) Here again, there can be no doubt that any testimony offered by Dr. Sinatra about novel opinions is subject to mandatory exclusion per Rule 37(c)(1) absent a finding of substantial justification or harmlessness.

The Court should find that neither exception applies. The fact that Dr. Sinatra "just didn't have time" to perform this research before he prepared his report cannot provide substantial justification for this failure. *See* Fed. R. Evid. 37(c)(1). Nor does the balance of the *Pennypack* factors support excusing this failure:

- *Pennypack* Factor (1): Dr. Sinatra has rendered his opinion on certain secondary factors that Depomed has proffered to show non-obviousness. As such, Dr. Sinatra's opinion is likely to address validity of the asserted patent claims, which is one of the key issues that will be addressed in this litigation.



- *Pennypack* Factors (2) – (4): Depomed will have no opportunity to vet these theories prior to trial. And because this case is on the eve of trial and the 30 month stay is nearly up, it is impossible for Depomed to cure this prejudice. *See* Fed. R. Evid. 403 advisory committee notes (1970) (“[T]he granting of a continuance is a more appropriate remedy than exclusion of the [unfairly surprising] evidence.”).
- *Pennypack* Factors (5) and (6): Dr. Sinatra’s explanation for why he did not do this work before simply does not carry the day. Simply put, if Dr. Sinatra did not have the time to do a complete job, Actavis should not have retained him.

On balance, these factors favor exclusion.

As with testimony by Drs. Flanagan and Mayersohn about undisclosed opinions, Rule 403 compels exclusion of testimony of undisclosed opinions by Dr. Sinatra for reasons of unfair surprise. (*See* Section IV(B), *supra*.)

## **VI. THE COURT SHOULD EXCLUDE ANY EXPERT TESTIMONY PROFFERED BY ACTAVIS IN SUPPORT OF ITS INDEFINITENESS DEFENSE**

Actavis’s Statement of Legal Issues includes the question: “Whether Actavis has shown by clear and convincing evidence that the asserted claims of the ’280 patent (*i.e.*, claims 1, 12, 14 and 45) are invalid as indefinite under 35 U.S.C. § 112, with respect to the claim element ‘of a size exceeding the pyloric diameter in the fed mode’?” (Ex. 17.) Actavis asserted this theory in its invalidity contentions, (Ex. 12 at 168), but none of Actavis’s experts provided any opinions to support this theory,

either in their reports or during deposition.<sup>6</sup> Actavis has indicated that it intends to move the Court for leave to amend its invalidity contentions as to this defense based solely on statements by a Depomed expert taken out of context.<sup>7</sup> Depomed anticipates that at trial Actavis may attempt to buttress its ill-founded theory<sup>8</sup> with new expert testimony that has not been previously disclosed to Depomed in either Actavis's experts' reports or during its experts' depositions. As such, Rule 37(c)(1) should mandate exclusion of any proffered expert testimony, and Rule 403 supports exclusion, for the same reasons as explained above for why the Court should exclude the reply opinions of Dr. Flanagan and Dr. Mayersohn and the undisclosed additional opinions of Dr. Sinatra.

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<sup>6</sup> Dr. Friend noted that he did not understand the Court's construction for "oval," but did not do the same for this term. (Ex. 6 at 167:13-23.) Dr. Friend's silence on the alleged indefiniteness of this term indicates that this defense is likely a frivolous one.

<sup>7</sup> As of the date on which these Motions were filed, Actavis had not sought leave. Depomed has indicated it will oppose any such motion.

<sup>8</sup> During claim construction, Actavis set forth a proposed construction for this term. (ECF No. 251 at 9.) Accordingly, by admission, the term is not "insolubly ambiguous," which is the standard for finding a challenged term definite. *E.g.*, *Datamize, LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1347 (Fed. Cir. 2005.) In any event, indefiniteness is a question of law for the Court for which no expert testimony is required. *See id.*

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